

Claims:

1. A recombinant polynucleotide comprising at least one regulatory element derived from intron 3 of the PSM gene and a sequence encoding a heterologous polypeptide.
2. A recombinant polynucleotide according to claim 1 in which the recombinant polynucleotide further comprises a promoter.
3. A recombinant polynucleotide according to claim 2 in which the promoter is located upstream from and is operably linked to the sequence encoding the heterologous polypeptide.
4. A recombinant polynucleotide according to claim 2 or claim 3 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.
5. A recombinant polynucleotide according to claim 4 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.
6. A recombinant polynucleotide according to claim 5 in which the promoter active in the prostate is a PSM promoter.
7. A recombinant polynucleotide according to any one of claims 1 to 6 in which the regulatory element is an enhancer element.
8. A recombinant polynucleotide according to claim 7 in which the enhancer element comprises
  - (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
  - (b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

9. A recombinant polynucleotide according to claim 7 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
10. A recombinant polynucleotide according to claim 7 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
11. A recombinant polynucleotide according to any one of claims 1 to 10 in which the polynucleotide comprises two or more regulatory elements derived from intron 3 of the PSM gene.
12. A recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and an insertion site into which a coding sequence is optionally inserted, the insertion site being adjacent to and downstream of the promoter.
13. A recombinant expression cassette according to claim 12 in which the regulatory element is located adjacent to the promoter.
14. A recombinant expression cassette according to claim 12 or claim 13 in which the regulatory element is upstream of the promoter.
15. A recombinant expression cassette according to any one of claims 12 to 14 in which the regulatory element is an enhancer element.
16. A recombinant expression cassette according to claim 15 in which the enhancer element comprises
  - (a) a sequence comprising nucleotides 14.045 to 15.804, nucleotides 14.760 to 15.804, nucleotides 14.760 to 16.575 or nucleotides 14.045 to 16.575 of the PSM gene; or
  - (b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

17. A recombinant expression cassette according to claim 15 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
18. A recombinant expression cassette according to claim 15 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
19. A recombinant expression cassette according to any one of claims 12 to 18 in which the expression cassette comprises two or more regulatory elements derived from intron 3 of the PSM gene.
20. A recombinant expression cassette according to any one of claims 12 to 19 in which the expression cassette comprises a dimer or higher multimer comprising two or more regulatory elements derived from intron 3 of the PSM gene.
21. A recombinant expression cassette according to any one of claims 12 to 20 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.
22. A recombinant expression cassette according to claim 21 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.
23. A recombinant expression cassette according to claim 22 in which the promoter active in the prostate is a PSM promoter.
24. A recombinant expression cassette according to any one of claims 12 to 23 in which the expression cassette further comprises a polyadenylation signal located downstream from and operably linked to the coding sequence or downstream from the insertion site.

25. A recombinant expression cassette according to claim 24 in which the polyadenylation signal is the SV40 polyadenylation signal or the bovine growth hormone polyadenylation signal.
26. An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising
- (a) a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11, or
  - (b) a nucleic acid sequence which hybridises under high stringency to the sequence defined in paragraph (a).
27. An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising
- (a) a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11, or
  - (b) a nucleic acid sequence which hybridises under high stringency to the sequence defined in paragraph (a).
28. A recombinant polynucleotide comprising an isolated nucleic acid molecule of claim 26 or claim 27.
29. A vector comprising an isolated nucleic acid molecule as claimed in claim 26 or claim 27.
30. A vector according to claim 29 which further comprises a gene encoding a selectable marker.
31. A vector according to claim 29 or claim 30 in which the vector is a human adenovirus Type 5 or ovine adenovirus.
32. A method for directing expression of a coding sequence in a cell, the method comprising introducing into the cell a recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the regulatory element and promoter direct expression of the coding sequence.

33. A method according to claim 32 in which the regulatory region is an enhancer element.

34. A method according to claim 33 in which the enhancer element comprises

(a) a sequence comprising nucleotides 14.045 to 15.804, nucleotides 14.760 to 15.804, nucleotides 14.760 to 16.575 or nucleotides 14.045 to 16.575 of the PSM gene; or

(b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

35. A method according to claim 33 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

36. A method according to claim 33 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

37. A method according to any one of claims 32 to 36 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

38. A method according to claim 37 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

39. A method according to claim 38 in which the promoter active in the prostate is a PSM promoter.

40. A method according to any one of claims 32 to 39 in which the cell is selected from the group consisting of a prostate cell, a bladder cell, a breast cell or a vascular endothelial cell.

41. A method according to any one of claims 32 to 40 in which the cell is a vascular endothelial cell.
42. A method for the treatment of cancer which method comprises administering to a subject a recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the regulatory element and promoter direct expression of the coding sequence.
43. A method according to claim 42 in which the regulatory region is an enhancer element.
44. A method according to claim 43 in which the enhancer element comprises
- (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
  - (b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).
45. A method according to claim 43 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
46. A method according to claim 43 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.
47. A method according to any one of claims 42 to 46 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.
48. A method according to claim 47 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

49. A method according to claim 48 in which the promoter active in the prostate is a PSM promoter.
50. A method according to any one of claims 42 to 49 in which the cell is selected from the group consisting of a prostate cell, a bladder cell, a breast cell or a vascular endothelial cell.
51. A method according to any one of claims 42 to 50 in which the cell is a vascular endothelial cell.
52. A method according to any one of claims 42 to 50 in which the cell is a prostate cell.
53. A method according to any one of claims 42 to 52 in which the coding sequence encodes the enzyme purine nucleoside phosphorylase (PNP).